The WireSafe™
Implementation Support Pack for Provider Organisations
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Introduction

This document has been compiled by Drs Peter Young and Maryanne Mariyaselvam (Consultant Intensivist and Clinical Fellow, Queen Elizabeth Hospital, King’s Lynn) and the Oxford Academic Health Science Network (AHSN), to assist provider organisations in implementing the WireSafe™.

The device is part of the NHS Innovation Accelerator (NIA), having been recognised as providing an evidence-based solution to a key healthcare challenge. The WireSafe™ has been developed by clinicians at the Queen Elizabeth Hospital, King’s Lynn with the aim of preventing the never event of retained CVC guidewires. The Oxford AHSN sees the WireSafe™ as a critical innovation that has the potential to significantly reduce patient harm. This Oxford AHSN Implementation Support Pack aims to provide Trusts with all the necessary information to implement this device, providing clinicians and project leads with a step by step guide of how to implement the WireSafe™. The pack includes a number of resources to help simplify the process of implementation including a summary document, outline business case, guidance for procurement, PowerPoint presentations for communicating internally with stakeholders, and advice on how to handle challenges to adoption and overcome potential barriers to implementation.

The guidance in this document is based on the experiences in the east of England. Differences in practice, protocols and systems at different Trusts may mean that processes vary slightly. If this is the case, please do share these differences with the contacts at the Oxford AHSN for future learning and to help other partner organisations.
Overview of Implementation Process

Below is an outline process for implementing the WireSafe™ that has been developed based on the experience of other Trusts. The process is made up of 2 core elements: engagement and building the case for adoption; and procurement, training and introducing devices into practices.

Step 1: Engage Clinical Team

Key Points

- Clinical engagement is a crucial first step in ensuring there is a willingness to adopt the WireSafe™.
- The Summary Document in this section provides a good starting point for discussion with both clinical and managerial teams.
- A summary PowerPoint presentation is also provided in the Implementation Support Pack for leads to present back to clinical and managerial teams on the opportunity provided by the WireSafe™.
- Common clinical concerns or queries have been captured in the “Potential Barriers to Implementation and Mitigating Action” section of the pack. Any other queries can be directed to your AHSN contacts who will support in addressing these issues.
### Summary Overview

**The WireSafe™**  
**Summary Document**

| Summary of Device | • For use during central venous catheter (CVC) insertion procedures  
| | • The WireSafe™ introduces a forcing function at the crucial point in the procedure, as only the guidewire can be used to unlock the procedure pack (allowing access to the suture, suture holder and antimicrobial dressing)  
| | • It is impossible to complete the procedure without removing the guidewire and as such despite possible distractions within the environment, the operator is always reminded and required to remove the guidewire  
| | • Guidewire must be removed from the patient to complete the procedure  
| | • The procedure pack doubles as a sharps disposal container for increased convenience and safety of staff  
| | • Promotes patient safety by preventing the potential of a never event occurring (retention of guidewire) and the subsequent harm and complications caused, additional procedures required and increased length of stay  
| | • The WireSafe™ received a Highly Commended Award at the National Patient Safety Awards 2016 and won the Association of Anaesthetist award |

| Patient Safety / Experience | Guidewires account for the second most common foreign object retention in the NHS, occurring in 1 in 3000 procedures. This can lead to very serious complications for patients, such as embolism of the wire to the heart, causing arrhythmias, vascular damage, thrombosis and has a reported mortality of up to 20%. There is associated increased expenditure for the Trust in terms of additional procedures required to remove the guidewire, a safety investigation to determine the root cause, additional costs in education and training programmes for the clinical staff to prevent the error and the Trust’s reputational cost. Furthermore, this has the potential for litigation which has been estimated at approximately £24k on average per successful case.  
| | The WireSafe™ addresses this risk and improves patient safety, by using the guidewire as a key to unlock the procedure pack to complete the procedure, this ensuring the guidewire is removed from the patient. By introducing this forcing function at a crucial point in the procedure the potential for the guidewire to be left in situ, and thereby a never event occurring, has been dramatically reduced. |

| Clinical Effectiveness | The device does not alter the basics of how the CVC insertion procedure is carried out but adds a safety design element to the procedure to prevent the possibility of a guidewire being retained.  
| | A randomised controlled forced error simulation study compared the WireSafe™ to the standard equipment. Participants were given a stressful scenario whereby a colleague had been urgently called away mid-CVC insertion. The WireSafe™ device lead to 0% guidewire retention in the WireSafe™ group compared to 80% retention in the standard group. |

| Operational Performance / Efficiency | The current preventative measures require ongoing staff training and additional staff time to record and administer a system of monitoring to prevent a rare event. When a never event does occur, a root-cause investigation must be undertaken to determine how/why |
The WireSafe™
Summary Document

The error occurred and ensure corrective measures are implemented, such as teaching and training of staff. This is a significant burden to Trusts in terms of staff time and financial resources.

By dramatically reducing the potential for the guidewire to be retained, the WireSafe™ device gives confidence to clinicians and Trusts that such a never event will not occur.

### Financial Analysis

**Cost of Device**

<table>
<thead>
<tr>
<th>Device</th>
<th>Cost per Unit (£)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>WireSafe™</td>
<td>**</td>
<td>- Single use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- All but eradicates potential for never event of guidewire being left in patient occurring</td>
</tr>
<tr>
<td>Current standard of care</td>
<td>35</td>
<td>- Single use</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Removal of guidewire dependent on individuals and therefore human error will occur</td>
</tr>
</tbody>
</table>

**Cost** will vary depending on how the WireSafe™ is purchased. Pennine Healthcare will provide the WireSafe™ ready packed with suture, suture holder, scissors, dressings and pen for £15 each. However other providers can supply the WireSafe™ with contents tailored to individual Trust requirements, for which the costs will vary.

**Savings associated with eliminating never events**

NHS Litigation Authority has estimated the litigation for retained central guidewires at £800k over the last 10 years, which covers 33 successful cases. Therefore, it can be estimated the litigation cost per never event is approximately £24k. Although this figure does not account for those cases that were not pursued or were unsuccessful.

While there is a cost to introducing the WireSafe™, a safety innovation, the potential costs (additional procedures, increased length of stay, potential litigation) from a never event occurring far outweigh the cost difference. By engineering out the potential for a guidewire being retained, there can be true confidence in improved patient safety.

### Workforce Implications

- Procurement requires liaison of clinicians with supplier for exact requirements
- No changes to the way current services are organised or delivered are needed
- The device is easy to use and requires minimal training

### Device available from

Devices can be ordered from Pennine Healthcare or Qualitech Healthcare:

- [www.penninehealthcare.co.uk](http://www.penninehealthcare.co.uk)
- [www.qualitechhealthcare.co.uk/products.html](http://www.qualitechhealthcare.co.uk/products.html)

Contact:
- Nicki Dill: n.dill@qualitechhealthcare.co.uk
- Megan Turner: m.turner@qualitechhealthcare.co.uk
The WireSafe™
Summary Document

<table>
<thead>
<tr>
<th>Relevant Links</th>
<th>Full clinical information and training videos are available at: <a href="http://www.KLIPSuk.com">www.KLIPSuk.com</a></th>
</tr>
</thead>
</table>

**PowerPoint Presentation**
To support clinical leads in making the case to clinical and managerial teams a slide deck has been put together to demonstrate the benefits of the device, how the device can be implemented and what stakeholders can expect during implementation. The slide deck is available as an embedded file in the online file, or alternatively by emailing james.rose@oxfordahsn.org or alison.gowdy@oxfordahsn.org

**Step 2: Business Case**

For adoption of the WireSafe™ a formal business case submission may be required. An outline business case template has been included in this implementation document and leads can find an electronic version available as a word document in the electronic resources which can be adapted to meet local requirements.

**Business Case Template**

<table>
<thead>
<tr>
<th>Improving Patient Safety - Implementation of the WireSafe™</th>
</tr>
</thead>
</table>

7
<table>
<thead>
<tr>
<th>Executive Sponsor</th>
<th>{insert}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Author</td>
<td>{insert}</td>
</tr>
<tr>
<td>Date</td>
<td>{insert}</td>
</tr>
<tr>
<td><strong>Summary of service development</strong></td>
<td>To implement the WireSafe™ device within the Intensive Care Unit and theatres, thereby improving patient safety for approximately {insert approx. annual number of patients who have a CVC} patients per annum. Retained guidewires account for the second most common foreign object retention in the NHS, occurring in 1 in 3000 procedures. This can lead to very serious complications for patients. The WireSafe™ is a unique system designed specifically to prevent guidewires being retained during central venous catheter insertion procedures. The innovation introduces a forcing function at the crucial point in the procedure, utilising the guidewire as a key to unlock the WireSafe™ procedure pack and access the contents to complete the procedure. Therefore, the user is prevented from completing the procedure without removing the guidewire. The WireSafe™ promotes patient safety by dramatically reducing the potential for a never event occurring (retention of guidewire), the subsequent harm and complications caused, and additional procedures required to remove the guidewire.</td>
</tr>
<tr>
<td>Link to Trust’s strategic aims</td>
<td>{insert}</td>
</tr>
<tr>
<td>Link to department’s annual plan</td>
<td>{insert}</td>
</tr>
<tr>
<td>Change in activity (IP / OP)</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Change in staffing</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Change in income</td>
<td>Not applicable</td>
</tr>
<tr>
<td>Change in costs</td>
<td>{insert}</td>
</tr>
</tbody>
</table>

### 1. Strategic Overview

Guidewires account for the second most common foreign object retention in the NHS, and is reported to occur twice a month in the NHS. However, the reported incidence in the literature is 1 in 3000 procedures, therefore it is well known this mistake is under reported. Retained guidewires can lead to very serious complications for patients, such as embolism of the wire to the heart causing arrhythmias, vascular damage, thrombosis and has a reported mortality of up to 20%. There is associated increased expenditure for the Trust in terms of additional procedures required to remove the guidewire, a safety
investigation to determine the root cause, additional costs in education and training programmes for clinical staff to prevent the error and the Trust’s reputational cost.

This error also has the potential for litigation, with the NHS Litigation Authority estimating litigation costs for retained central guidewires over the last 10 years at £800k. This figure covers 33 successful cases, which equates to approximately £24k per never event. However, this figure does not account for those cases that were not pursued or were unsuccessful.

The impact of such an error on the doctor carrying out the procedure must not be underestimated. The majority of these procedures are carried out by junior doctors and there are cases of doctors leaving the profession due to the profound personal affect this error has had.

The WireSafe™ box also becomes the sharps container for the items used during the procedure, which can then be safely transported to the sharps bins, and thereby improves sharps safety. A very conservative estimate of the number of sharps injuries occurring every year in the NHS is 40,000, however the Royal College of Nursing estimated the figure to be 100,000 per annum. One sharps injury can cost a Trust between £300 and £14,000 depending on the risk of cross-injection (NHS Employers, December 2015).

At {insert Trust} there have been {insert number} reported incidents of retained guidewires over the last 3 years, and {insert number} cases of near misses {if recorded}.

Prevention and patient safety are key priority areas across the NHS, and this business case proposes a device that will address each of these.

2. Summary of Proposed Option

The WireSafe™ is intended for use in patients undergoing central venous catheter insertion. The device is designed so that it is impossible for the procedure to be completed without removing the guidewire, and as such despite possible distractions within the operating environment, the operator is always reminded and required to remove the guidewire. The guidewire is required to unlock the procedure pack, allowing access to the suture, suture holder and antimicrobial dressing.

The WireSafe™ promotes patient safety by dramatically reducing the potential for a retained guidewire occurring, and as such reduces the potential for harm and complications that can occur with this never event.

3. Option Appraisal

Option 1 – Do Nothing
This option maintains the status quo and would not see the WireSafe™ implemented within critical care. There would be no change to the equipment used to carry out a
central venous catheter insertion and as such the potential for the never event of a retained guide wire would remain. Clinical errors that would have been prevented by the WireSafe™ may have the responsibility transferred from the individual clinician to the organisation, thereby increasing executive responsibility and litigation costs to the Trust.

**Option 2 – Implement the WireSafe™ in Theatres and Critical Care (preferred option)**
This option would see the WireSafe™ implemented within critical care and theatres, and in doing so the potential for retained central guidewires would be dramatically reduced. Staff and patients would have assurance that such an error is minimised, and the Trust would have assurance that never events would be prevented. Patient safety would be improved and clinicians carrying out these procedures would be protected and supported to perform their job safely.

4. **Activity Implications for Preferred Option**
- The WireSafe™ will not impact on the number of patients requiring central venous catheter insertion procedures
- There will be minimal impact on the staff using the WireSafe™
- Minimal training is required

5. **Financial Analysis for Preferred Option**

<table>
<thead>
<tr>
<th></th>
<th>Current Practice</th>
<th>WireSafe™</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of CVC</td>
<td>{insert number}</td>
<td>{insert number – this will be the same}</td>
</tr>
<tr>
<td>insertion procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>per annum</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cost per pack</td>
<td>{insert cost}</td>
<td>{insert cost}</td>
</tr>
<tr>
<td><strong>Total annual cost</strong></td>
<td>{insert cost}</td>
<td>{insert cost}</td>
</tr>
</tbody>
</table>

* The contents of the WireSafe™ can be tailored to individual Trusts, with cost varying depending on contents. This figure has been used following discussion of our requirements with the supplier

The WireSafe™ costs {insert cost} more / less than current practice.

<table>
<thead>
<tr>
<th></th>
<th>{insert number}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of reported retained central guidewires from 2014/15 – 2016/17</td>
<td></td>
</tr>
</tbody>
</table>
| Estimated additional expenditure required due to retained guidewire | Within the Trust this would include:  
- Transfer of patient and specialist skills (interventional radiologists) to remove the guidewire
- Cost of a root cost analysis
- Education and training programmes highlighting the importance of preventing the never event
- Instigation of safety solution: checklist, 2-person procedure and inclusion into the Trust protocol |
Additional total expenditure from 2014/15 – 2016/17

This additional expenditure would be avoided with the use of the WireSafe™.

### 6. Project Implementation

<table>
<thead>
<tr>
<th>Action / Milestone</th>
<th>Responsible Person</th>
<th>Timeframe</th>
</tr>
</thead>
<tbody>
<tr>
<td>Agree business case</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Training sessions for staff to ensure all staff aware of WireSafe™ and how to use it (provided by supplier)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Place order for WireSafe™ and contents with supplier</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 7. Risk Management / Service Development Sensitivities

<table>
<thead>
<tr>
<th>Risks</th>
<th>Mitigation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Addition expenditure required</td>
<td>The WireSafe™ offers an evidence-based patient safety device that ensures central guidewires cannot be retained. The increased expenditure will be mitigated from the assurance that the need for additional procedures, further patient treatment costs, safety and educational programmes for staff will be prevented.</td>
</tr>
</tbody>
</table>
Step 3: Procurement of Devices

Once there is agreement from clinical and managerial teams to proceed, leads will need to work with procurement and finance. An overview of the procurement process has been provided to help leads at each Trust understand the steps needed to make the WireSafe™ available for ordering (Figure 2 Error! Reference source not found.).

In addition, the key information for procurement has been collated into a simple one page document for leads at each Trust to share with procurement at the appropriate time (see Information for Procurement).

![Figure 2 Overview Process for Procurement of the WireSafe™](image-url)
Information for Procurement

Leads at each Trust can use the text and details below to share relevant information with Procurement department.

After approval from clinical leads and management to proceed, ICU would like to procure and implement a novel product: the WireSafe™. The unit is an adjunct to existing CVC packs and provides an additional safety feature which prevents the never event of retained guidewires. We have gathered the relevant information below which we hope is enough for you to proceed. Please let us know if further information is required.

Projected numbers of CVC procedures each year: [to be completed by trust]

Suppliers able to provide goods to specification:

1. For standalone, ready-made packs
   a. Pennine Healthcare

   **Supplier Details**

   Pennine Healthcare  
   City Gate  
   London Road  
   Derby  
   DE24 8WY  
   United Kingdom  
   Tel: +44 (0) 1332 794880  
   Fax. +44 (0) 1332 794890  
   VAT Number: to be provided  
   GHX Number: to be provided  
   Supplier Classification: Large Supplier

   b. Qualitech Healthcare

   **Supplier Details:**

   Qualitech Healthcare Limited  
   16 Cordwallis Park  
   Clivemont Rd  
   Maidenhead  
   Berkshire  
   SL6 7BU  
   Tel: +44 (0)1628 854042  
   info@qualitechhealthcare.co.uk  
   VAT Number: 180535219  
   GHX Number: GS1 – GLN5060456660000 – SID4GOV 464885  
   Supplier Classification: Small to Medium Enterprise (SM/E) SM  
   Product code: 1004WS
Step 4: Schedule and Deliver Training
The WireSafe™ is an intuitive simple procedural pack, that does not require a large amount of training. However, as with any change of practice, local practice development leads should be involved in understanding how the WireSafe™ is used and how the department is likely to get the most from its use.

Once an order for the WireSafe™ has been submitted, responsible project leads and practice development nurses may wish to contact the supplier to schedule a meeting with a sales representative. A rep will be happy to run a short train the trainer session on the device although this may not be necessary. An excellent training resource has been developed by staff at Queen Elizabeth Hospital, King’s Lynn which can be accessed using the following link https://www.youtube.com/watch?v=nHB16v5uT5s

Clinical leads will want to ensure all clinical who will be using the WireSafe™ are aware of the change and are comfortable using the device.

Step 5: Introduce the WireSafe™ into practice
Once training has been delivered, and stock has been received leads should look to introduce the WireSafe™ into practice. Specifying a date at which only the WireSafe™ will be available would provide a defined timeframe for staff to become accustomed to the new device whilst allowing old stock to be run down to minimise wastage.

Step 6: Decommission Alternatives
The current CVC packs can be used initially concurrently with the WireSafe™ during the introductory / training phase, which will minimise wastage.

The contents within the WireSafe™ can be tailored to individual Trust requirements. Alternatively, the WireSafe™ can be ordered as an individual procedure pack: WireSafe™ (which will include suture, suture holder, scissors, dressings) and opened onto the CVC trolley, in combination with the current CVC sterile insertion pack. [Note, clinicians will be required to inform the CVC pack supplier to remove suture, suture holder, scissors, dressings from the current kit].
Step 7: Monitor and Optimise Usage

Once implemented continual monitoring and reinforcement to ensure use of the WireSafe™ becomes standard of care. Retained guidewires and foreign objects is a reportable event and impact on patient safety should be easy to monitor.

Baseline Data Requirements

The table below outlines the data required both to inform the business case and to provide the baseline against which the impact of the device can be measured. The system by which the data can be collated is given, although it is recognised that this may vary by Trust (Table 1).

Table 1 Baseline Data Requirements – WireSafe™

<table>
<thead>
<tr>
<th>Data requirement</th>
<th>System/department to provide data</th>
<th>Time period for which data is required</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Reported number of never events due to retention of CVC guidewire</td>
<td>Incident Reporting System / NHS England</td>
<td>Last 3 years</td>
</tr>
<tr>
<td>2. Number of near misses relating to retention of CVC guidewire</td>
<td>Incident Reporting System</td>
<td>Last 3 years</td>
</tr>
<tr>
<td>3. Annual number of patients requiring a central line</td>
<td>ICU / Theatres</td>
<td>Last 3 years</td>
</tr>
</tbody>
</table>

Potential Barriers to Implementation and Mitigating Action

Implementation of innovation is rarely straightforward and in many cases barriers and challenges faced at one Trust will be similar to those experienced at other Trusts. In the table below, some of the most common issues arising from implementation have been captured along with how best to circumvent or overcome this hurdle (Table 2).
<table>
<thead>
<tr>
<th>Potential Barriers to Implementation</th>
<th>Mitigating Action</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.</strong> Additional cost required to implement the innovation represents a cost pressure to the Trust</td>
<td>The WireSafe™ offers an evidence-based patient safety device that prevents central guidewire retention. The increased expenditure will be mitigated from assurance that such an error is dramatically reduced and therefore additional procedures and increased length of stay will not be required. The WireSafe™ not only improves patient safety but reduces the potential for increased expenditure following such an error.</td>
</tr>
<tr>
<td><strong>2.</strong> Training is required before the device can be implemented</td>
<td>A minimal amount of training is required to ensure staff are accustomed to the device</td>
</tr>
<tr>
<td><strong>3.</strong> The WireSafe™ will require changes in clinical practice</td>
<td>The WireSafe™ will require minimal changes in clinical practice. Procedures will be carried out as they currently are, but the WireSafe™ will ensure the operator is reminded to remove the guidewire.</td>
</tr>
<tr>
<td><strong>4.</strong> There is a large number of the current CVC packs in stock</td>
<td>Current CVC packs can be used initially concurrently with the WireSafe™ during the introductory / training phase.</td>
</tr>
<tr>
<td><strong>5.</strong> The Trust is tied into a contract with our current supplier for CVC kits</td>
<td>If the current supplier is unable to provide a patient safety product (i.e. the WireSafe™), the Trust can break the contract without consequence.</td>
</tr>
<tr>
<td>Potential Barriers to Implementation</td>
<td>Mitigating Action</td>
</tr>
<tr>
<td>-------------------------------------</td>
<td>------------------</td>
</tr>
<tr>
<td>6. The WHO checklist is already in place, which should prevent retained guidewires</td>
<td>The WHO checklist was mandated in 2010, but it has not stopped the incidence of never events rising. Some Trusts have introduced various methods to prevent never events, such as checklists, two person procedures, supervision of trainees, documenting removal, checking the trolley. Despite such initiatives never events do still occur. This is because these initiatives rely on the human operator behaving perfectly at all times, yet we know at some point humans do fail. These initiatives also have a cost implication to the Trust. The WireSafe™ has been designed to engineer out the possibility of the guidewire being retained, but introducing a forcing function at the crucial point in the procedure. This means the procedure cannot be completed without the removal of the guidewire to unlock the procedure pack.</td>
</tr>
</tbody>
</table>
Contacts
For further information, please contact:

**Alison Gowdy**
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Email: alison.gowdy@oxfordahsn.org

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Clinical Innovation Adoption Manager, Oxford AHSN
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Consultant Intensivist, Queen Elizabeth Hospital, King’s Lynn
NIA Fellow
Email: peteryoung101@gmail.com

**Dr Maryanne Mariyaselvam**
Clinical Fellow, Queen Elizabeth Hospital, King’s Lynn
NIA Fellow
Email: m.mariyaselvam@nhs.net